Calculation of the Minimal Important Clinical Difference of the Lysholm and IKDC Scores After Anterior Cruciate Ligament Reconstruction

Cálculo da Mínima diferença clínica importante dos escores Lysholme IKDC após reconstrução do ligamento cruzado anterior

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Rev Bras Ortop 2023;58(1):79–84.

Abstract

Objective To calculate the minimal important clinical difference (MICD) value for the Lysholm and International Knee Documentation Committee (IKDC) scores in a sample of patients submitted to anterior cruciate ligament reconstruction.

Methods Primary, observational, retrospective, analytical study of participants submitted to anterior cruciate ligament reconstruction from March 2019 to December 2020 by the same surgeon, with a minimum follow-up of 6 months, analysis of knee function in the pre- and postoperative period by the Lysholm and IKDC scores, and answer to an anchor question at 6 months postoperatively for the calculation of the MICD of each score.

Results A total of 59 patients participated in the study, with a mean age of 27.1 ± 5.7 years old. In the comparison between pre- and postoperative scores of all groups, there was an increase in values with statistical significance after intervention. The MICD was 5.5 for the Lysholm score, and the MICD value for the IKDC score could not be determined.

Conclusion For the Lysholm score, the calculation of the MICD value by the anchor question method in the sample evaluated was 5.5. It was not possible to determine the value of the MICD for the IKDC score.

Keywords
- anterior cruciate ligament
- anterior cruciate ligament reconstruction
- knee joint
- reproducibility of results
- surveys and questionnaires

Work developed at the Orthopedics and Traumatology Service, Hospital Universitário da Universidade Federal de Juiz de Fora, Juiz de Fora, MG, Brazil.

received
October 14, 2021
accepted
July 26, 2022
article published online
October 13, 2022

DOI https://doi.org/10.1055/s-0042-1756330.
ISSN 0102-3616.

Thieme Revinter Publicações Ltda., Rua do Matoso 170, Rio de Janeiro, RJ, CEP 20270-135, Brazil

Resumo

Objetivo Calcular o valor da mínima diferença clinicamente importante (MDCI) para os escores de Lysholm e International Knee Documentation Commitee (IKDC) na amostra de pacientes submetidos a reconstrução de ligamento cruzado anterior.

Métodos Estudo primário, observacional, retrospectivo, analítico, de participantes submetidos a reconstrução do ligamento cruzado anterior no período de março de 2019 a dezembro de 2020, pelo mesmo cirurgião, com seguimento mínimo de 6 meses, análise da função do joelho no período pré e pós-operatório pelos escores de Lysholm e IKDC, e resposta a uma pergunta âncora aos 6 meses de seguimento pós-operatório, para o MDCI de cada escore.

Resultados Participaram do estudo 59 pacientes, com média de idade de 27,1 ± 5,7 anos. Na comparação dos escores pré- e pós-operatórios de todos os grupos, observa-se aumento dos valores com significância estatística após a intervenção. A MDCI foi de 5,5 para o escore de Lysholm, não tendo sido possível determinar o valor para o IKDC.

Conclusão O cálculo do valor da MDCI pelo método da pergunta âncora, na amostra avaliada, foi de 5,5 para o escore de Lysholm. Não foi possível determinar o valor da MDCI para o IKDC.

Palavras-chave

- ligamento cruzado anterior
- reconstrução do ligamento cruzado anterior
- articulação do joelho
- reprodutibilidade dos testes
- inquéritos e questionários

Introduction

Anterior cruciate ligament (ACL) reconstruction is certainly one of the surgical procedures most performed by knee surgeons.[1–3] The success of the procedure can be evaluated not only by the clinical recovery of the patient, but also by more objective parameters.[4,5] The Patient Reported Outcomes Measurement Information System (PROMIS) are metrics that assess clinical outcomes in patients undergoing treatment and consider aspects of the health of the patient from their perspective and not only in the clinical observation of the evaluator.[6] The International Knee Documentation Commitee (IKDC) and the Lysholm scales are examples of PROMIS used in functional clinical evaluation of patients with ACL injury undergoing surgical treatment.[7–9]

The interpretation of the information obtained by PROMIS includes the statistical analysis of the parameter of the minimal important clinical difference (MICD).[10,11] The MICD is defined as the minimum value for a change to be considered significant for the patient.[12] This is a unique psychometric data for each measure of PROMIS, showing to be a reliable tool for determining the results and understanding the effects of a surgical treatment.[10] The MICD can be obtained by three different methods: distribution, previous clinical trial experience and clinical anchor questions.[10,13] This correlates the values of the scores selected for each patient with the answer to the anchor question of each one, which allows describing the degree of clinical change after the intervention.[12,13] Thus, the evaluation considers the patient's perception, without interference from the researcher or loss of information.[13]

The literature does not describe the MICD value for the IKDC and Lysholm scales in Brazilian patients undergoing ACL reconstruction. The knowledge of this value in a national sample can parameterize the results of surgical treatment in a more reliable way in the literature. The present study aims to determine the MICD for the IKDC and Lysholm scales in patients undergoing ACL reconstruction.

Methods

This is a primary, retrospective analytical observational study, approved by the research ethics committee of the institution (CAAE: 07044818.1.0000.5133) and written according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[14]

Participants were selected consecutively from March 2019 to December 2020. The inclusion criteria were adult Brazilian individuals $\leq$60 years old, without degenerative changes in knee imaging and with complete ACL injury with indication for surgical treatment. The minimum postoperative follow-up was 6 months. Patients operated for other traumas, submitted to previous ACL reconstruction, those who were unable to follow the study instructions or who declared themselves unavailable to participate were excluded. The participants signed the free and informed consent form.

The preoperative evaluation included anamnesis and physical examination performed by a full member of the Brazilian Society of Knee Surgery, plain radiography, and magnetic resonance imaging (MRI) to confirm the diagnosis of total ACL[3] rupture and identify associated lesions. Patients with indication for surgical treatment responded to the IKDC and Lysholm questionnaires.[7,8] The surgical technique consisted of arthroscopic reconstruction of the ACL with a graft of the tendons of the semitendinous and gracile muscles prepared in a quadruple manner. The graft was fixed with absorbable interference screws.[15] After the surgical procedure, the patients were referred for physical therapy rehabilitation, following the protocol of the

institution, whose approach is divided into four progressive phases, composed of some degree of control of inflammatory signs, gain of knee mobility, gait stimulation, muscle strengthening, sensorimotor stimulation, demonstration of accelerated gait without pain, and training of sports gestures.

The patients were followed-up on serial outpatient visits, monthly, and, in the 6-month evaluation after surgical treatment, they underwent functional evaluation by the Lysholm and IKDC scales. The anchor method, described by Revicki et al., was used to calculate the minimal important clinical difference.[13] The anchor question was asked: "Compared to before surgery, how would you rate your knee now?" The answers were graded in the following options: "much better", "a little better", "almost the same", "a little worse", and "much worse". From the answer to this anchor question, the grouping of patients was performed and those who answered "almost the same" and "a little worse" were classified as "group without change", while those who answered "a little better" were classified as "minimal change group". The participants who answered the anchor question with "much better" or "much worse" were excluded from the MICD analysis because they had more than minimal changes, as described by Revicki et al.[13] For the calculation of the MICD, the IKDC and Lysholm scores of the "no change" and "minimal change" groups were compared.[13,14] Receiver Operating Characteristic (ROC) curve was used to define the point that best discriminated the two groups evaluated in the MICD calculation. The point chosen was the one that maximized specificity and sensitivity. The area under the ROC curve (AUC) was calculated to evaluate reliability. An AUC value between 0.7 and 0.8 is considered acceptable and a value of 0.8 to 0.9 is considered excellent.[16]

The sample size calculation was made using G*Power 3.1 software, with unicaudal test, high effect size ($d = 0.80$), 80% test power and 95% confidence.[16,17] The sample needed to detect the MICD was 42 patients, who composed the minimal change group ($n = 17$) and the no change group ($n = 25$).

The data were presented by means of mean and standard deviation (SD) (quantitative variables) and percentages (qualitative variables). Data normality was assessed by the Kolmogorov-Smirnov test. The paired Student t-test was used to compare differences in PROMIS between pre- and postoperative periods. A repeated measurement analysis of variance (ANOVA) was used to assess the interaction between groups (minimal difference versus no change) and measurement (preoperatively versus postoperatively). The effect size (Te) was evaluated by Cohen d, with the following classification: small = 0.20 to 0.49; moderate = 0.50 to 0.79; high $\geq$ 0.80.[17] All analyses were made on the statistical software IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, NY, USA). A p-value < 0.05 was adopted for statistical significance.

Results

Fifty-nine patients participated in the study, with ages ranging from 18 to 42 years old. Of these, 36 (61%) were male and 26 (39%) were female. The mean age was 27.1 ± 5.7 years old. The predominant laterality of the lesion was on the right side ($n = 37$; 62.7%). Statistically significant improvements were observed in the functional scores of the IKDC and Lysholm scales in the postoperative period when comparing all groups (►**Table 1**). It is estimated that the increase in functional scores in the postoperative period was on average 3.8 to 7 points (IKDC) and from 4.9 to 12.9 points (Lysholm) with 95% confidence. From the clinical point of view, the size of the observed effect suggests that the magnitude of the improvement was moderate in both the IKDC ($d = 0.72$) and Lysholm ($d = 0.70$) scales.

►**Table 2** shows the distribution of the answers of the patients to the anchor question. For the calculation of the MICD, 2 groups were considered, the "no change group ", with 24 patients, and the "minimal change group", with 17 patients.

No statistically significant differences were observed in the functional scores from the pre- and postoperative periods for the patients in the "no change" and "minimal change" groups (►**Table 3**). Although the change in Lysholm between the groups is not significant, from the clinical point of view, the effect size (ES) observed was moderate, being higher in the minimal change group.

Therefore, based on the anchor method, the AUC defined by the ROC curve was 0.69 (0.52 to 0.86); $p = 0.04$) for the Lysholm scale. The cutting point for the MCID of the Lysholm scale was 5.5 points (76.5% sensitivity and 71.0% specificity) (►**Fig. 1**). However, for IKDC, it was not possible to determine a cutoff point for MICD in the present sample (AUC = 0.46 [0.28–0.65]; $p = 0.70$).

Discussion

The present study aimed to calculate the MICD for the Lysholm score in subjects submitted to ACL reconstruction

Table 1 Values of the IKDC and Lysholm functional scores of the participants ($n = 59$)

	Pre-	Post-	95%CI (difference)	*p-value*	ES
IKDC	55.3 ± 7.6	60.8 ± 7.4	3.8–7.0	0.001	0.72
Lysholm	67.5 ± 12.7	76.4 ± 11.4	4.9–12.9	< 0.001	0.70

Abbreviations: 95%CI, 95% confidence interval of the difference between pre- and postaverages; IKDC, International Knee Documentation Committee Subjective Knee Evaluation Form; ES, effect size (Cohen d).
Source: The authors.

Table 2 Quantity and percentage of the answers of the participants to the anchor question

Question	$n = 59$, n (%)
Compared to before surgery. how would you evaluate your knee now?	
Much better	14 (23.7)
A little better	17 (28.8)
Almost the same	18 (30.5)
A little worse	6 (10.2)
Much worse	4 (6.8)

Source: The authors

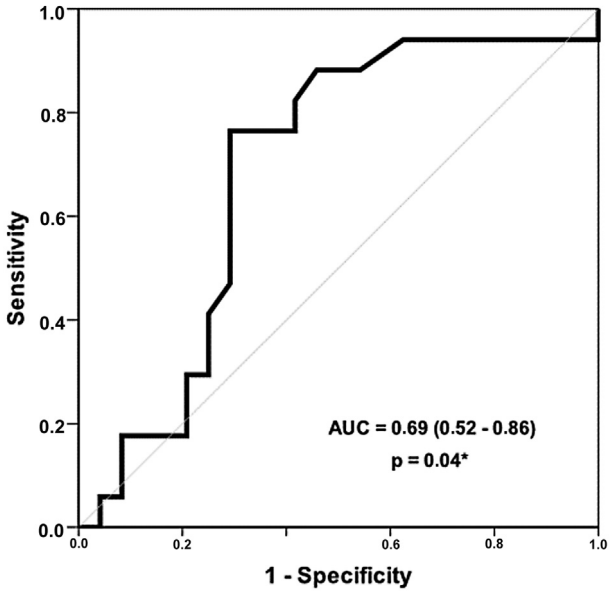

Fig. 1 Area under the curve (AUC) of the Lysholm score between patients in the "no change" and "minimal change" group ($n = 41$). Source: The authors.

and obtained a value of 5.5 points. This value is close to the results of Nwachukwu et al.,[18] Jones et al.,[19] and Weng et al.,[20] who reported the values of 10.0, 10.1, and 8.9, respectively. In the Brazilian literature, no studies were found that defined an MICD value for the scores evaluated in the present study.

Regarding the IKDC scale, in the present study, it was not possible to determine an MICD cutoff point. The reasons for the inability to determine it would be the short follow-up period and the size of the evaluated sample. The sample calculation was based on the size of the effect,[17] proposed by the study by Ogura et al.[16] ($n = 86$), which included patients with ACL injury in association with other pathologies, such as osteochondral or meniscal injury, which were repaired during surgical intervention in a single time. Thus, the perception of change by the patient is higher, favoring the impact of treatment in a wider amplitude rather than a more homogeneous sample, with ACL rupture without associated lesions. Risberg et al.[9] described that the IKDC scale showed significant improvement 1 to 2 years after ACL reconstruction, indicating the inability of this score to detect changes in short periods. Nwachukwu et al.[18] ratified this information and concluded that the change was smaller at 6 months than at 12 months after surgery. These authors calculated the MICD using the IKDC scale and, for ACL reconstruction, they found the value of 16.7 in 2 years.

Demographically, most participants are male, with a mean age of 27 years old, which is in line with other studies on the surgical treatment of ACL injuries.[9,18,21] The increase in functional scores in the postoperative period was on average 3.8 to 7 points (IKDC) and 4.9 to 12.9 points (Lysholm), similar to that presented by Collins et al.,[22] showing a variation of 2.4 to 4.6 in the IKDC scale and 9.7 to 12.5 in the Lysholm scale. Significant clinical improvement of these scores occurs in 6 months and would not change after this period.[23]

When comparing the pre- and postoperative scores of all groups, there was an increase in scores with statistical significance after intervention ($p < 0.05$). However, when comparing these values in the "minimal change group" and in the "no change group", the initial difference observed

Table 3 Values of functional scores of the groups "no change" and "minimal change"

	No change ($n = 24$)	Minimal change ($n = 17$)	95%CI (difference)	*p-value*	ES
IKDC					
Pre-	54.1 ± 7.9	56.7 ± 5.7	- 1.9–7.2	0.25	0.38
Post-	60.5 ± 8.0	62.3 ± 6.3	- 2.9–6.5	0.44	0.25
Δ	6.4 ± 5.6	5.6 ± 7.8	- 5.0–3.4	0.70	0.12
Lysholm					
Pre-	71.4 ± 10.2	69.0 ± 11.8	- 9.4–4.5	0.48	0.22
Post-	74.4 ± 11.3	77.6 ± 7.5	- 3.1–9.6	0.28	0.34
Δ	2.9 ± 12.3	8.6 ± 9.8	- 1.6–12.9	0.12	0.52

Abbreviations: 95%CI, 95% confidence interval of the difference between pre- and postaverages; IKDC, International Knee Documentation Committee Subjective Knee Evaluation Form; ES, effect size (Cohen d).
Source: The authors.

is not maintained; after all, the greatest variation in the PROMIS score occurs in patients with significant change, who were included in the group "much better", which was excluded for the calculation of the MICD. Su et al.[24] and Weng et al.[20] observed a phenomenon similar to that mentioned in their work for these same scores.

As limitations of the present study, we have the method chosen to calculate the MICD, which should ideally be performed in comparison with another method, such as distribution or previous clinical trial experience,[10,13] but these require a larger sample size than the one evaluated. The sample was not sufficient for analysis of the AUC for the IKDC scale. Moreover, it presents limitation of the characteristic of the PROMIS used in the study and the understanding of the participants, even with previous guidance to the answers. However, the present study is a pioneer in the search for MICD values for the IKDC and Lysholm scores in patients undergoing ACL reconstruction at the national level.

Conclusion

In the evaluated sample, the MICD value for the Lysholm score is 5.5 points, while the score was undetectable for the IKDC score. Functional analysis by scores increased postoperatively from 3.8 to 7 points (IKDC) and 4.9 to 12.9 points (Lysholm).

Financial Support
The present study received no financial support from either public, commercial, or not-for-profit sources.

Conflict of Interests
The authors have no conflict of interests to declare.

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